Listed below are clean copies of the amended claims. Marked-up copies of the amended claims are provided in an accompanying document.

1. (amended) A device used in surgical procedures to reconstruct an enlarged left ventricle of a human heart, the device comprising:

a shaper, having a size and shape substantially similar to the size and shape of an appropriate left ventricle, wherein the size of the appropriate left ventricle is less than the size of the enlarged left ventricle, and wherein the shaper is adapted to be temporarily placed into the enlarged left ventricle during a surgical procedure.

14. (amended) The device of claim 13 wherein the wire mesh is made of nitinol.

32. (amended) The system of claim 1, wherein the shaper is substantially ellipsoid in shape.

33. (amended) The system of claim 1, wherein the shaper is substantially conical in shape.

34. (amended) The system of claim 1, wherein the shaper is substantially pear shaped.

35. (amended) The system of claim 1, wherein the shaper is substantially tear drop shaped.

45. (amended) A device used in surgical procedures to reconstruct an enlarged left ventricle of a human heart, the device comprising:

a shaper, having a size and shape which substantially defines the size and shape of the appropriate left ventricle, wherein the shaper is to be placed into the enlarged left ventricle during a surgical procedure.

Please add the following claims.

49. (new) A shaping system, comprising:

a shaper positionable in a left ventricle of a heart during use, wherein the shaper is

configurable to expand to a predetermined shape in the left ventricle during use, and wherein the predetermined shape acts as a pattern to reconstruct the left ventricle about the shaper during use.

50. (new) The system of claim 49, wherein the shaper comprises an expandable balloon.

51. (new) The system of claim 49, wherein the shaper comprises an expandable balloon, and wherein the expandable balloon has a wall thickness of about 0.02 inches to about 0.08 inches.

52. (new) The system of claim 49, wherein the shaper comprises an expandable balloon, and wherein the expandable balloon has a wall thickness of less than about 0.08 inches.

53. (new) The system of claim 49, wherein the shaper comprises an expandable balloon, wherein the expandable balloon has a wall thickness, and wherein the wall thickness selectively varies as a function of the expansion of the balloon.

54. (new) The system of claim 49, wherein the shaper comprises a predetermined contour.

55. (new) The system of claim 49, wherein the shaper is configured to contain at least one fluid in at least a portion of the shaper.

56. (new) The system of claim 49, wherein the shaper is configured to contain at least one fluid in at least a portion of the shaper, and wherein the fluid is configurable to expand the shaper to the predetermined shape.

57. (new) The system of claim 49, wherein the shaper is configured to contain at least one fluid in at least a portion of the shaper, wherein the fluid is configurable to expand the shaper to the predetermined shape, and wherein the fluid is a gel.

58. (new) The system of claim 49, wherein the shaper is configured to contain at least one fluid in at least a portion of the shaper, wherein the fluid is configurable to expand the shaper to

the predetermined shape, and wherein the fluid comprises silicone.

59. (new) The system of claim 49, wherein the shaper is configured to inhibit expansion beyond a predetermined point.

60. (new) The system of claim 49, wherein the shaper is configured to inhibit distortion of the predetermined shape when expanded.

61. (new) The system of claim 49, further comprising a tube coupled to the shaper, wherein the tube is configurable to convey a fluid to the shaper.

62. (new) The system of claim 49, further comprising a tube coupled to the shaper, wherein the tube is configurable to convey a fluid to the shaper from a pressurized fluid reservoir.

63. (new) The system of claim 49, further comprising a tube coupled to the shaper, wherein the tube is configurable to convey a fluid to the shaper from a pressurized fluid reservoir, and further comprising a valve coupled to the tube, wherein the valve is configurable to maintain a pressure of the fluid.

64. (new) The system of claim 49, wherein the shaper has a short axis and a long axis.

65. (new) The system of claim 49, wherein the shaper is expanded to the predetermined shape.

66. (new) The system of claim 49, wherein the shaper has a short axis and a long axis, and wherein the ratio of the short axis to the long axis is from about 0.3 to about 0.7.

67. (new) The system of claim 49, wherein the shaper is substantially ellipsoid in shape.

68. (new) The system of claim 49, wherein the shaper is substantially conical in shape.

69. (new) The system of claim 49, wherein the shaper is substantially pear shaped.

70. (new) The system of claim 49, wherein the shaper is substantially tear drop shaped.

71. (new) The system of claim 49, wherein the shaper comprises a wire mesh.

72. (new) The system of claim 49, wherein the shaper further comprises at least two flexible elongated members, and wherein at least one of the elongated members is configurable to bend forming the predetermined shape.

73. (new) The system of claim 49, wherein the shaper comprises nitinol.

74. (new) A shaping system, comprising:

a shaper positionable in a left ventricle of a heart during use, wherein the shaper is configurable to expand to a predetermined shape during use, wherein the predetermined shape is different than a geometry of the left ventricle, and wherein the predetermined shape acts as a pattern to reconstruct the left ventricle about the shaper during use.

75. (new) The system of claim 74, wherein the shaper comprises an expandable balloon.

76. (new) The system of claim 74, wherein the shaper comprises an expandable balloon, and wherein the expandable balloon has a wall thickness of about 0.02 inches to about 0.08 inches.

77. (new) The system of claim 74, wherein the shaper comprises an expandable balloon, and wherein the expandable balloon has a wall thickness of less than about 0.08 inches.

78. (new) The system of claim 74, wherein the shaper comprises an expandable balloon, wherein the expandable balloon has a wall thickness, and wherein the wall thickness selectively varies as a function of the expansion of the balloon.

79. (new) The system of claim 74, wherein the shaper comprises a predetermined contour.

80. (new) The system of claim 74, wherein the shaper is configured to contain at least one fluid in at least a portion of the shaper.

81. (new) The system of claim 74, wherein the shaper is configured to contain at least one fluid in at least a portion of the shaper, and wherein the fluid is configurable to expand the shaper to the predetermined shape.

82. (new) The system of claim 74, wherein the shaper is configured to contain at least one fluid in at least a portion of the shaper, wherein the fluid is configurable to expand the shaper to the predetermined shape, and wherein the fluid is a gel.

83. (new) The system of claim 74, wherein the shaper is configured to contain at least one fluid in at least a portion of the shaper, wherein the fluid is configurable to expand the shaper to the predetermined shape, and wherein the fluid comprises silicone.

84. (new) The system of claim 74, wherein the shaper is configured to inhibit expansion beyond a predetermined point.

85. (new) The system of claim 74, wherein the shaper is configured to inhibit distortion of the predetermined shape when expanded.

86. (new) The system of claim 74, wherein the shaper is expanded to the predetermined shape.

87. (new) The system of claim 74, further comprising a tube coupled to the shaper, wherein the tube is configurable to convey a fluid to the shaper.

88. (new) The system of claim 74, further comprising a tube coupled to the shaper, wherein the tube is configurable to convey a fluid to the shaper from a pressurized fluid reservoir.

89. (new) The system of claim 74, further comprising a tube coupled to the shaper, wherein the

tube is configurable to convey a fluid to the shaper from a pressurized fluid reservoir, and further comprising a valve coupled to the tube, wherein the valve is configurable to maintain a pressure of the fluid.

90. (new) The system of claim 74, wherein the shaper has a short axis and a long axis.

91. (new) The system of claim 74, wherein the shaper has a short axis and a long axis, and wherein the ratio of the short axis to the long axis is about 0.3 to about 0.7.

92. (new) The system of claim 74, wherein the shaper is substantially ellipsoid in shape.

93. (new) The system of claim 74, wherein the shaper is substantially conical in shape.

94. (new) The system of claim 74, wherein the shaper is substantially pear shaped.

95. (new) The system of claim 74, wherein the shaper is substantially tear drop shaped.

96. (new) The system of claim 74, wherein the shaper comprises a wire mesh.

97. (new) The system of claim 74, wherein the shaper further comprises at least two flexible elongated members, and wherein at least one of the elongated members is configurable to bend forming the predetermined shape.

98. (new) The system of claim 74, wherein the shaper comprises nitinol.

99. (new) A shaping system, comprising:

a shaper positionable in a left ventricle of a heart during use, wherein the shaper comprises a hollow, wherein the shaper is configurable to expand to a predetermined shape during use, and wherein the predetermined shape acts as a pattern to reconstruct the left ventricle about the shaper during use; and

a gel positionable in the hollow, wherein the gel is configurable to expand the shaper to

the predetermined shape during use.

100. (new) The system of claim 99, wherein the gel comprises silicone.

101. (new) The system of claim 99, further comprising a tube coupled to the hollow, wherein the tube is configurable to convey the gel to the cavity of the shaper.

102. (new) The system of claim 99, further comprising a tube coupled to the hollow, wherein the tube is configurable to convey the gel to the hollow from a pressurized gel reservoir.

103. (new) The system of claim 99, further comprising a tube coupled to the hollow, wherein the tube is configurable to convey the gel to the hollow from a pressurized gel reservoir, and further comprising a valve coupled to the tube, wherein the valve is configurable to maintain a pressure of the gel.

104. (new) A shaping system, comprising:

a shaper positionable in a left ventricle of a heart during use, wherein the shaper comprises a hollow, wherein the shaper is configurable to expand to a predetermined shape during use, and wherein the predetermined shape acts as a pattern to reconstruct the left ventricle about the shaper during use; and

an expander positionable in the hollow of the shaper during use, wherein the expander is configurable to expand the shaper to the predetermined shape during use.

105. (new) The system of claim 104, wherein the expander is configured to contain at least one fluid in at least a portion of the expander.

106. (new) The system of claim 104, wherein the expander is configured to contain at least one fluid in at least a portion of the expander, and wherein the fluid is configurable to expand the expander.

107. (new) The system of claim 104, wherein the expander is configured to contain at least

one fluid in at least a portion of the expander, wherein the fluid is configurable to expand the expander, and wherein the fluid is a gel.

108. (new) The system of claim 104, wherein the expander is configured to contain at least one fluid in at least a portion of the expander, wherein the fluid is configurable to expand the expander, and wherein the fluid comprises silicone.

109. (new) The system of claim 104, wherein at least the shaper is configured to inhibit expansion beyond a predetermined point.

110. (new) The system of claim 104, wherein at least the shaper is configured to inhibit distortion of the predetermined shape when expanded.

111. (new) The system of claim 104, further comprising a tube coupled to the expander, wherein the tube is configurable to convey a fluid to the expander.

112. (new) The system of claim 104, further comprising a tube coupled to the expander, wherein the tube is configurable to convey a fluid to the expander from a pressurized fluid reservoir.

113. (new) The system of claim 104, further comprising a tube coupled to the expander, wherein the tube is configurable to convey a fluid to the expander from a pressurized fluid reservoir, and further comprising a valve coupled to the tube, wherein the valve is configurable to maintain a pressure of the fluid.

114. (new) A shaping system, comprising:

a shaper positionable in a left ventricle of a heart during use, wherein the shaper comprises a hollow, wherein the shaper is configurable to expand to a predetermined shape during use, and wherein the predetermined shape acts as a pattern to reconstruct the left ventricle about the shaper during use;

an expander positionable in the hollow of the shaper during use, wherein the expander is

configurable to expand the shaper to the predetermined shape during use; and

a fluid positionable between the outer surface of the expander and an inner surface of the shaper during use.

115. (new) The system of claim 114, wherein the expander is configured to contain at least one fluid in at least a portion of the expander.

116. (new) The system of claim 114, wherein the expander is configured to contain at least one fluid in at least a portion of the expander, and wherein the fluid is configurable to expand the expander.

117. (new) The system of claim 114, wherein the expander is configured to contain at least one fluid in at least a portion of the expander, wherein the fluid is configurable to expand the expander, and wherein the fluid is a gel.

118. (new) The system of claim 114, wherein the expander is configured to contain at least one fluid in at least a portion of the expander, wherein the fluid is configurable to expand the expander, and wherein the fluid comprises silicone.

119. (new) The system of claim 114, wherein at least the shaper is configured to inhibit expansion beyond a predetermined point.

120. (new) The system of claim 114, wherein at least the shaper is configured to inhibit distortion of the predetermined shape when expanded.

121. (new) The system of claim 114, further comprising a tube coupled to the expander, wherein the tube is configurable to convey a fluid to the expander.

122. (new) The system of claim 114, further comprising a tube coupled to the expander, wherein the tube is configurable to convey a fluid to the expander from a pressurized fluid reservoir.

123. (new) The system of claim 114, further comprising a tube coupled to the expander, wherein the tube is configurable to convey a fluid to the expander from a pressurized fluid reservoir, and further comprising a valve coupled to the tube, wherein the valve is configurable to maintain a pressure of the fluid.

124. (new) A shaping system, comprising:

a shaper positionable in a left ventricle during use, wherein the shaper is configurable to expand to a predetermined shape during use, and wherein the predetermined shape acts as a pattern to reconstruct the left ventricle about the shaper during use; and

at least one or more spacers positioned on the outer surface of the shaper.

125. (new) The system of claim 124, wherein the spacers are configured to inhibit perforation of the shaper during use.

126. (new) The system of claim 124, wherein the shaper comprises an expandable balloon.

127. (new) The system of claim 124, wherein the spacers are coupled to the outer surface of the shaper.

128. (new) The system of claim 124, wherein the spacers are formed as part of the outer surface of the shaper.

129. (new) The system of claim 124, wherein the shaper is configurable to contain at least one fluid in at least a portion of the shaper.

130. (new) The system of claim 124, wherein the shaper is configurable to contain at least one fluid in at least a portion of the shaper, and wherein the fluid is configurable to expand the shaper to the predetermined shape.

131. (new) The system of claim 124, wherein the shaper is configurable to contain at least one

fluid in at least a portion of the shaper, wherein the fluid is configurable to expand the shaper to the predetermined shape, and wherein the fluid is a gel.

132. (new) The system of claim 124, wherein the shaper is configurable to contain at least one fluid in at least a portion of the shaper, wherein the fluid is configurable to expand the shaper to the predetermined shape, and wherein the fluid comprises silicone.

133. (new) The system of claim 124, wherein the shaper is configured to inhibit expansion beyond a predetermined point.

134. (new) The system of claim 124, wherein the shaper is configured to inhibit distortion of the predetermined shape when expanded.

135. (new) The system of claim 124, further comprising a tube coupled to the shaper, wherein the tube is configurable to convey a fluid to the shaper.

136. (new) The system of claim 124, further comprising a tube coupled to the shaper, wherein the tube is configurable to convey a fluid to the shaper from a pressurized fluid reservoir.

137. (new) The system of claim 124, further comprising a tube coupled to the shaper, wherein the tube is configurable to convey a fluid to the shaper from a pressurized fluid reservoir, and further comprising a valve coupled to the tube, wherein the valve is configurable to maintain a pressure of the fluid.

138. (new) A shaping system, comprising:

a shaper positionable in a left ventricle of a heart during use, wherein the shaper is configurable to expand to a predetermined shape during use, wherein the predetermined shape acts as a pattern to reconstruct the left ventricle about the shaper during use, and wherein a first portion of the shaper has a first wall thickness;

wherein a second portion of the shaper comprises a second wall thickness greater than the first wall thickness, and wherein the shaper is configured to inhibit perforation of the

shaper during use.

139. (new) The system of claim 138, wherein the second portion comprises a self sealing material.

140. (new) The system of claim 138, wherein the second portion comprises a self sealing material, and wherein the self sealing material comprises self sealing latex rubber.

141. (new) A shaping system, comprising:

a shaper positionable in a left ventricle of a heart during use, wherein the shaper comprises at least two elongated members, wherein at least one of the elongated members is configurable to bend to form a predetermined shape during use, wherein the predetermined shape is different than a geometry of the left ventricle, and wherein the predetermined shape acts as a pattern to reconstruct the left ventricle about the shaper during use.

142. (new) The system of claim 141, further comprising an expander positioned in a void during use, wherein the void is defined by at least two of the elongated members, wherein the expander is configurable to expand the shaper to the predetermined shape during use.

143. (new) The system of claim 141, further comprising a lock configurable to inhibit movement of the elongated members upon engagement of the lock.

144. (new) The system of claim 141, wherein the shaper is configured to inhibit expansion beyond a predetermined point.

145. (new) The system of claim 141, wherein the shaper is configured to inhibit distortion of the predetermined shape when expanded.

146. (new) A shaping system, comprising:

a shaper having a size substantially similar to the size of an appropriate left ventricle of a heart, wherein the shaper is adapted to be temporarily placed into an enlarged left ventricle

during use.

147. (new) The system of claim 146, wherein the shaper comprises an expandable balloon.

148. (new) The system of claim 146, wherein the shaper comprises a predetermined contour.

149. (new) The system of claim 146, wherein the shaper is configured to contain at least one fluid in at least a portion of the shaper, and wherein the fluid is configurable to expand the shaper to a predetermined shape.

150. (new) The system of claim 146, wherein the shaper is configured to inhibit expansion beyond a predetermined point.

151. (new) The system of claim 146, wherein the shaper is configured to inhibit distortion of a predetermined shape when expanded.

152. (new) The system of claim 146, further comprising a tube coupled to the shaper, wherein the tube is configurable to convey a fluid to the shaper from a pressurized fluid reservoir.

153. (new) The system of claim 146, wherein the shaper is expanded to a predetermined shape.

154. (new) The system of claim 146, wherein the shaper has a short axis and a long axis, and wherein the ratio of the short axis to the long axis is from about 0.3 to about 0.7.

155. (new) The system of claim 146, wherein the shaper comprises a wire mesh.

156. (new) The system of claim 146, wherein the shaper further comprises at least two flexible elongated members, and wherein at least one of the elongated members is configurable to bend forming a predetermined shape.

157. (new) A shaping system, comprising:

a shaper having a shape substantially similar to the shape of an appropriate left ventricle of a heart, wherein the shaper is adapted to be temporarily placed into an enlarged left ventricle during use.

158. (new) The system of claim 157, wherein the shaper comprises an expandable balloon.

159. (new) The system of claim 157, wherein the shaper comprises a predetermined contour.

160. (new) The system of claim 157, wherein the shaper is configured to contain at least one fluid in at least a portion of the shaper, and wherein the fluid is configurable to expand the shaper to a predetermined shape.

161. (new) The system of claim 157, wherein the shaper is configured to inhibit expansion beyond a predetermined point.

162. (new) The system of claim 157, wherein the shaper is configured to inhibit distortion of a predetermined shape when expanded.

163. (new) The system of claim 157, further comprising a tube coupled to the shaper, wherein the tube is configurable to convey a fluid to the shaper from a pressurized fluid reservoir.

164. (new) The system of claim 157, wherein the shaper is expanded to a predetermined shape.

165. (new) The system of claim 157, wherein the shaper has a short axis and a long axis, and wherein the ratio of the short axis to the long axis is from about 0.3 to about 0.7.

166. (new) The system of claim 157, wherein the shaper comprises a wire mesh.

167. (new) The system of claim 157, wherein the shaper further comprises at least two

flexible elongated members, and wherein at least one of the elongated members is configurable to bend forming a predetermined shape.

168. (new) A method for reshaping a left ventricle of a heart, comprising:
positioning a shaper in the left ventricle;
expanding the shaper to a predetermined shape; and
reshaping at least a portion of the left ventricle about the shaper such that at least a portion of the left ventricle substantially conforms to the predetermined shape of the shaper.

169. (new) The method of claim 168, wherein at least a portion of the left ventricle substantially mimics the predetermined shape of the shaper.

170. (new) The method of claim 168, further comprising:
determining a demarcation line between non-viable tissue and viable tissue;
excluding at least some of the non-viable tissue;
placing at least one suture along at least a portion of the demarcation line; and
pulling the suture such that the left ventricle is pulled around the shaper.

171. (new) The method of claim 170, wherein the determining of the demarcation line further comprises engaging a wall of the left ventricle of a beating heart to sense tactile feedback.

172. (new) The method of claim 170, wherein the determining of the demarcation line further comprises visually determining akinetic and viable tissue.

173. (new) The method of claim 170, wherein the determining of the demarcation line further comprises detecting electrical pulses from viable tissue.

174. (new) The method of claim 168, further comprising suturing a patch to an interior of the left ventricle.

175. (new) The method of claim 170, further comprising suturing a patch along at least a

portion of one of the demarcation lines.

176. (new) The method of claim 168, further comprising excluding scar tissue from the viable tissue.

177. (new) A method for reshaping a left ventricle of a heart, comprising:

positioning a shaper in the left ventricle;

positioning a gel in a hollow of the shaper to expand the shaper to a predetermined shape; and

reshaping at least a portion of the left ventricle about the shaper such that at least a portion of the left ventricle substantially conforms to the predetermined shape of the shaper.

178. (new) The method of claim 177, wherein at least a portion of the left ventricle substantially mimics the predetermined shape of the shaper.

179. (new) The method of claim 177, further comprising:

determining a demarcation line between non-viable tissue and viable tissue;

excluding at least some of the non-viable tissue;

placing at least one suture along at least a portion of the demarcation line; and

pulling the suture such that the left ventricle is pulled around the shaper.

180. (new) The method of claim 179, wherein the determining of the demarcation line further comprises engaging a wall of the left ventricle of a beating heart to sense tactile feedback.

181. (new) The method of claim 179, wherein the determining of the demarcation line further comprises visually determining akinetic and viable tissue.

182. (new) The method of claim 179, wherein the determining of the demarcation line further comprises detecting electrical pulses from viable tissue.

183. (new) The method of claim 177, further comprising suturing a patch to an interior of the

left ventricle.

184. (new) The method of claim 179, further comprising suturing a patch along at least a portion of one of the demarcation lines.

185. (new) The method of claim 177, further comprising excluding scar tissue from the viable tissue.

186. (new) A method for reshaping a left ventricle of a heart, comprising:

positioning a shaper in the left ventricle;

expanding an expander positioned in a hollow of the shaper to expand the shaper to a predetermined shape; and

reshaping at least a portion of the left ventricle about the shaper such that at least a portion of the left ventricle substantially conforms to the predetermined shape of the shaper.

187. (new) The method of claim 186, wherein at least a portion of the left ventricle substantially mimics the predetermined shape of the shaper.

188. (new) The method of claim 186, further comprising:

determining a demarcation line between non-viable tissue and viable tissue;

excluding at least some of the non-viable tissue;

placing at least one suture along at least a portion of the demarcation line; and

pulling the suture such that the left ventricle is pulled around the shaper.

189. (new) The method of claim 188, wherein the determining of the demarcation line further comprises engaging a wall of the left ventricle of a beating heart to sense tactile feedback.

190. (new) The method of claim 188, wherein the determining of the demarcation line further comprises visually determining akinetic and viable tissue.

191. (new) The method of claim 188, wherein the determining of the demarcation line further

comprises detecting electrical pulses from viable tissue.

192. (new) The method of claim 186, further comprising suturing a patch to an interior of the left ventricle.

193. (new) The method of claim 188, further comprising suturing a patch along at least a portion of one of the demarcation lines.

194. (new) The method of claim 186, further comprising excluding scar tissue from the viable tissue.

Response To Office Action Mailed November 8, 2002

A. Pending Claims

Claims 1-14 and 29-194 are currently pending. Claims 1, 14, 32-35, and 45 have been amended. Claims 49-194 are new.

B. Provisional Double Patenting Rejection

The Examiner provisionally rejected claims 1-14 and 29-48 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-28 of copending U.S. Patent Application No. 09/864,794. Applicant respectfully disagrees that the rejection is appropriate. Upon issuance of a patent for U.S. Patent Application No. 09/864,794 or the present application, or upon both applications being in condition for allowance but for the provisional double patenting rejection, Applicant will provide arguments for the inappropriateness of the double patenting rejection and/or provide a terminal disclaimer for the patent and/or patent applications.

C. The Claims Are Not Anticipated By Deslauriers Pursuant To 35 U.S.C. § 102(b)

The Examiner rejected claims 1-5, 8-12, 29-35, and 45-47 under 35 U.S.C. 102(b) as anticipated by U.S. Patent No. 5,255,678 to Deslauriers et al. (hereinafter "Deslauriers"). Applicant respectfully disagrees with these rejections.

The standard for "anticipation" is one of fairly strict identity. To anticipate a claim of a patent, a single prior source must contain all the claimed essential elements. Hybritech, Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 231 U.S.P.Q.81, 91 (Fed. Cir. 1986); In re Donahue, 766 F.2d 531,226 U.S.P.Q. 619,621 (Fed. Cir. 1985).

The Examiner states:

> Deslauriers et al disclose a balloon device 20 shaped and sized to be fitted within the left ventricle when inflated. The device further includes a tube 23 in fluid communication with the balloon 20, a valve 24, pressure gauge (column 8, line 65) and syringe 26. The purpose for which applicant intends the device to be used (i.e. a "shaper") fails to impose any objectively ascertainable structural distinctions from the device disclosed by Deslauriers et al.

Applicant respectfully disagrees that the purpose for which Applicant intends the device to be used fails to impose any objectively ascertainable structural distinctions from the device disclosed by Deslauriers.

Amended claim 1 describes a combination of features including: "a shaper, having a size and shape substantially similar to the size and shape of an appropriate left ventricle, wherein the size of the appropriate left ventricle is less than the size of the enlarged left ventricle, and wherein the shaper is adapted to be temporarily placed into the enlarged left ventricle during a surgical procedure." Amended claim 45 describes a combination of features including: "a shaper, having a size and shape which substantially defines the size and shape of the appropriate left ventricle, wherein the shaper is to be placed into the enlarged left ventricle during a surgical procedure." Applicant has amended claims 1 and 45 for clarification. Applicant respectfully submits the amendments to these claims do not substantively change the scope of the claims. Applicant submits that at least a shaper substantially equal in size and shape of an appropriate left ventricle adapted to be temporarily placed in an enlarged left ventricle and/or at least a

shaper which defines the size and shape of the appropriate left ventricle temporarily placed in an enlarged left ventricle during a surgical procedure, in combination with the other features of the claims, does not appear to be taught or suggested by the cited art.

Deslauriers discloses in column 4, lines 18-20, "It is therefore an aim of the present invention to provide an electrode balloon having a universal construction adaptable to any one of the cavities of the heart." Deslauriers further discloses:

> It is still a further aim of the present invention to provide a knitting for a particular one of the cardiac chambers which has a pattern adapted to confer to the electrode balloon a shape that will allow the same to contact when expanded the inner wall of the cardiac chamber for various volumes and shapes of the latter. (Deslauriers, column 4, lines 32-37).

In addition, Deslauriers discloses:

> The originality of the present electrode balloon lies in its ability to overcome the insertion restraints inherent to the introduction of the electrode balloon in either one of the ventricles by way of its respective auricle, and in its adaptability using the same basic structure to the different cardiac chambers. (Deslauriers, column 7, lines 14-19).

Deslauriers appears to teach or suggest a balloon capable of expanding to fill various sized chambers of a heart so that a knitted pattern of electrodes covering the balloon will make contact with the interior surface of the heart chamber. Deslauriers does not appear to teach or suggest a shaper of substantially equal size and shape of an appropriate left ventricle configurable to assist in reconstructing an enlarged left ventricle. Applicant submits Deslauriers does not appear to teach all of the features in claims 1 and 45 and the claims dependent thereon.

If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988). Applicant submits, however, that many of the claims dependent on claims 1 and 45 are separately patentable.

For example, the Examiner states, "In regards to claim 3, a partially inflated balloon may be further inflated." Claim 3 describes a combination of features including: "wherein when the balloon is in an inflated condition, the balloon cannot be substantially expanded." Applicant submits that claim 2 from which claim 3 depends substantially defines an "inflated condition" to be when "the balloon is a size and shape substantially equal to the size and shape of an appropriate left ventricle." Applicant submits that at least the quoted features of claim 3, in combination with the other features of the claim, do not appear to be taught by the cited art.

Claim 2 recites, in part "wherein the shaper comprises an expandable balloon, such that when the balloon is in a substantially inflated condition, the balloon is a size and shape substantially equal to the size and shape of an appropriate left ventricle." At least these features of claim 2, in combination with the other features of the claim, do not appear to be taught or suggested by the cited art.

Claim 4 recites, in part "wherein the balloon is in an inflated condition, the balloon maintains the shape of an appropriate left ventricle while being further inflated." At least these features of claim 4, in combination with the other features of the claim, do not appear to be taught or suggested by the cited art.

Claim 5 recites, in part "wherein the balloon is filled with fluid." At least these features of claim 5, in combination with the other features of the claim, do not appear to be taught or suggested by the cited art.

Claim 8 recites, in part "a tube in fluid communication with an interior of the balloon, a pressurized fluid reservoir in fluid communication with the tube, and a valve coupled to the tube for maintaining a pressure of the pressurized fluid." At least these features of claim 8, in combination with the other features of the claim, do not appear to be taught or suggested by the cited art.

Claim 9 recites, in part "a means to monitor the pressure of the pressurized fluid." At least these features of claim 9, in combination with the other features of the claim, do not appear

to be taught or suggested by the cited art.

Claim 10 recites, in part "wherein the pressurized fluid reservoir is a syringe." At least these features of claim 10, in combination with the other features of the claim, do not appear to be taught or suggested by the cited art.

Claim 11 recites, in part "a means to withdraw the pressurized fluid from the tube." At least these features of claim 11, in combination with the other features of the claim, do not appear to be taught or suggested by the cited art.

Claim 12 recites, in part "wherein the means to withdraw the pressurized fluid is a syringe." At least these features of claim 12, in combination with the other features of the claim, do not appear to be taught or suggested by the cited art.

Claim 29 recites, in part "having a non-circular shape." At least this feature of claim 29, in combination with the other features of the claim, do not appear to be taught or suggested by the cited art.

Claim 30 recites, in part "wherein the shaper has a short and a long axis." At least this feature of claim 30, in combination with the other features of the claim, do not appear to be taught or suggested by the cited art.

Claim 31 recites, in part "wherein the ratio of short to long axis is about 0.5." At least this feature of claim 31, in combination with the other features of the claim, do not appear to be taught or suggested by the cited art.

Amended claim 32 recites, in part "wherein the shaper is substantially ellipsoid in shape." At least this feature of claim 32, in combination with the other features of the claim, do not appear to be taught or suggested by the cited art.

Amended claim 33 recites, in part "wherein the shaper is substantially conical in shape."

At least this feature of claim 33, in combination with the other features of the claim, do not appear to be taught or suggested by the cited art.

Amended claim 34 recites, in part "wherein the shaper is substantially pear shaped." At least this feature of claim 34, in combination with the other features of the claim, do not appear to be taught or suggested by the cited art.

Amended claim 35 recites, in part "wherein the shaper is substantially tear drop shaped." At least this feature of claim 35, in combination with the other features of the claim, do not appear to be taught or suggested by the cited art.

Claim 46 recites, in part "wherein the shaper comprises an expandable balloon, such that when the balloon is substantially inflated, the balloon defines the size and shape of appropriate left ventricle." At least these features of claim 46, in combination with the other features of the claim, do not appear to be taught or suggested by the cited art. As discussed regarding claim 45, Applicant submits that Deslauriers does not appear to teach or suggest a balloon that when substantially inflated defines the size and shape of appropriate left ventricle.

Claim 47 recites, in part "wherein the balloon is in an inflated condition, the balloon maintains its shape which defines the intended left ventricle, while, being further inflated." At least these features of claim 47, in combination with the other features of the claim, do not appear to be taught or suggested by the cited art. As discussed regarding claim 45, Applicant submits that Deslauriers does not appear to teach or suggest a balloon that when substantially inflated defines the size and shape of appropriate left ventricle and while being further inflated.

D. <u>The Claims Are Not Anticipated By Swanson Pursuant To 35 U.S.C. § 102(e)</u>

The Examiner rejected claims 1, 13, 14, 29-35, and 45 under 35 U.S.C. 102(e) as anticipated by U.S. Patent No. 6,216,043 B1 to Swanson et al. (hereinafter "Swanson"). Applicant respectfully disagrees with these rejections.

The Examiner states:

> Swanson et al disclose an expandable device shaped and sized for a patient's left ventricle comprised a nitinol wire mesh 20. The manner in which applicant intends for the claimed device to used fails to impose any objectively ascertainable structural distinctions from the device disclosed by Swanson et al.

Applicant respectfully disagrees that the purpose for which Applicant intends the device to be used fails to impose any objectively ascertainable structural distinctions from the device disclosed by Swanson.

Claim 1 describes a combination of features including: "a shaper, having a size and shape substantially similar to the size and shape of an appropriate left ventricle, wherein the size of the appropriate left ventricle is less than the size of the enlarged left ventricle, and wherein the shaper is adapted to be temporarily placed into the enlarged left ventricle during a surgical procedure." Applicant submits that support for the amendment can be found at least in the specification on page 10, paragraph 48 "there is shown a shaping device 200 that allows the left ventricle to be reconstructed back to a pre-enlarged operating condition. When the surgeon uses shaping device 200 as a guide in reconstructing the left ventricle, the reconstructed heart can be formed closer to the size and shape of the pre-enlarged heart." "The shaping device may be of an "appropriate shape" for a patient. In other words, the shaping device may be of a shape similar to the shape of the left ventricle." (Specification, page 10, paragraph 49). Claim 45 describes a combination of features including: "a shaper, having a size and shape which substantially defines the size and shape of the appropriate left ventricle, wherein the shaper is to be placed into the enlarged left ventricle during a surgical procedure." Applicant submits that at least a shaper substantially equal in size and shape of an appropriate left ventricle adapted to be temporarily placed in an enlarged left ventricle and/or at least a shaper which defines the size and shape of the appropriate left ventricle temporarily placed in an enlarged left ventricle during a surgical procedure, in combination with the other features of the claims, do not appear to be taught or suggested by the cited art.

Swanson discloses in column 2, lines 19-23, "The spline elements exist in a

circumferentially spaced relationship about the hub axis defining angular intervals between adjacent spline elements. The spline elements are adapted to contact tissue within the interior body cavity." Swanson further discloses:

> An associated method deploys the axially asymmetric structure in an interior body region, which is preferable also axially asymmetric. The axially asymmetric structure makes it possible to position one or more diagnostic or therapeutic elements in conforming contact with tissue within asymmetric body cavities, such as a heart chamber.
> (Swanson, column 2, lines 38-44).

In addition, Swanson discloses:

> When deployed for use (as FIG. 1 shows)--which, in a preferred embodiment, is inside a heart chamber--the support assembly 20(1) of the probe 10(1) holds the electrodes 30 in contact against the endocardium. Due to its radial symmetry, the pattern density of electrodes 30 is generally the same wherever electrode-tissue contact occurs. Thus, the number of electrodes per unit area of endocardium contacted by the electrodes 30 is generally equal throughout the chamber.
> (Swanson, column 6, lines 39-47).

Swanson appears to teach or suggest a support structure capable of expanding to fill various sized chambers of a heart so that a pattern of electrodes covering the support structure will make contact with the interior surface of the heart chamber. Swanson does not appear to teach or suggest a shaper of substantially equal size and shape of an appropriate left ventricle configurable to assist in reconstructing an enlarged left ventricle. Applicant submits Swanson does not appear to teach all of the features in claims 1 and 45 and the claims dependent thereon.

If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988). Applicant submits, however, that many of the claims dependent on claims 1 and 45 are separately patentable.

For example, claim 33 recites, in part "wherein the shaper is substantially conical in

shape." At least this feature of claim 33, in combination with the other features of the claim, do not appear to be taught or suggested by the cited art.

Claim 13 recites, in part "wherein the shaper is a wire mesh of a predetermined shape." At least these features of claim 13, in combination with the other features of the claim, do not appear to be taught or suggested by the cited art.

Amended claim 14 recites, in part "wherein the wire mesh is made of nitinol." At least these features of claim 14, in combination with the other features of the claim, do not appear to be taught or suggested by the cited art.

Claim 29 recites, in part "having a non-circular shape." At least this feature of claim 29, in combination with the other features of the claim, do not appear to be taught or suggested by the cited art.

Claim 30 recites, in part "wherein the shaper has a short and a long axis." At least this feature of claim 30, in combination with the other features of the claim, do not appear to be taught or suggested by the cited art.

Claim 31 recites, in part "wherein the ratio of short to long axis is about 0.5." At least this feature of claim 31, in combination with the other features of the claim, do not appear to be taught or suggested by the cited art.

Claim 32 recites, in part "wherein the shaper is substantially ellipsoid in shape." At least this feature of claim 32, in combination with the other features of the claim, do not appear to be taught or suggested by the cited art.

Claim 34 recites, in part "wherein the shaper is substantially pear shaped." At least this feature of claim 34, in combination with the other features of the claim, do not appear to be taught or suggested by the cited art.

Claim 35 recites, in part "wherein the shaper is substantially tear drop shaped." At least this feature of claim 35, in combination with the other features of the claim, do not appear to be taught or suggested by the cited art.

E. The Claims Are Not Obvious Over Deslauriers Pursuant To 35 U.S.C. § 103(a)

The Examiner rejected claims 6 and 7 under 35 U.S.C. 103(a) as obvious over Deslauriers. Applicant respectfully disagrees with these rejections.

In order to reject a claim as obvious, the Examiner has the burden of establishing a *prima facie* case of obviousness. *In re Warner et al.*, 379 F.2d 1011, 154 U.S.P.Q. 173, 177-178 (C.C.P.A. 1967). To establish a *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 U.S.P.Q. 580 (C.C.P.A. 1974), MPEP § 2143.03.

The Examiner states:

> In regards to claim 6 and 7, Deslauriers et al, are silent as to the inflating fluid. The selection, however, of conventional medical balloon inflation fluids would have been obvious to the ordinary skilled artisan.

Applicant respectfully disagrees. Claim 6 describes a combination of features including: "wherein the fluid is a gel." Claim 7 describes a combination of features including: "wherein the gel is silicone." Applicant submits that at least the above quoted features of claims 6 and 7, in combination with the other features of the claims, do not appear to be taught or suggested by the cited art. Applicant respectfully submits that the Examiner's rejection of the features of claims 6 and 7 as obvious matters of choice or design may rely upon personal knowledge of the Examiner and therefore Applicant believes MPEP 2144.03 will apply. Pursuant to MPEP 2144.03, Applicant respectfully requests the Examiner to provide support for his assertion either by an affidavit or by references brought to the Applicant's attention. Otherwise, Applicants request this rejection be removed. *See, e.g.,* MPEP 2143.01.

F. Conclusion

Applicant submits that all claims are in condition for allowance. Favorable reconsideration is respectfully requested.

A Fee Authorization is enclosed to cover fees for additional claims. If any extension of time is required, Applicant hereby requests the appropriate extension of time. If any fees are required or have been overpaid, please appropriately charge or credit those fees to Deposit Account Number 50-1505/5838-00300/EBM.

Respectfully submitted,

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